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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,960	12/03/2003	James P. Beckham	297912006401	4367

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EXAMINER

MCCORKLE, MELISSA A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,960

Applicant(s)

BECKHAM, JAMES P.

Examiner

Melissa A. McCorkle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/9/04-10/18/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-17 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-17 of copending Application No. 10/726,464. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-12, 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamlin (5,270,086). Hamlin discloses a non-compliant medical balloon (fig 4), where the non-compliant medical balloon may be changed from a deflated state to an inflated state by increasing pressure applied to an interior surface of the balloon (abstract), comprising a first fiber layer (col 2 line 9), a second fiber layer over said first fiber layer such that the fibers of the first fiber layer and the fibers of the second fiber layer form an angle (fig 5, layers are angled), a binding layer that secures the first fiber layer to the second fiber layer (col 2 lines 55-68) so that the first and second fiber layers are

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restricted from substantial relative movement during inflation and deflation (see abstract – limited radial expansion, with the correct combination of materials it is capable of restricting movement during inflation and deflation), wherein the interior surface are of the non-compliant medical balloon remains substantially unchanged when the balloon changes form a deflated state to an inflated state (see abstract – with correct combination of materials col 3 lines 1-8, the balloon is capable of remaining unchanged when the balloon changes from a deflated to inflated state), wherein said first fiber layer comprises inelastic fibers (col 2 lines 31-68), wherein said first fiber layer comprises a plurality of first fibers (col 3 lines 1-8), further comprising an adhesive layer adhering to said first fiber layer (col 2 lines 12-30), wherein said second fiber layer comprises a plurality of parallel second fibers (col 3 lines 1-8), wherein said angle is substantially a right angle (fig 5), wherein said angle does not change when the balloon changes from a deflated state to an inflated state (see abstract – limited radial expansion, with the correct combination of materials it is capable of restricting movement during inflation and deflation), wherein said plurality of parallel first fibers are substantially parallel to the longitudinal axis of the balloon (fig 4), wherein said plurality of parallel second fibers are substantially transverse to the longitudinal axis of the balloon (fig 4), wherein said binding layer is a polymeric coating (col 2 lines 31-68), wherein said polymeric coating is formed of a polymer or copolymer (col 2 lines 31-68), wherein said angle is about 10 degrees (fig 4), further comprising a third fiber layer on said second fiber layer (col 2 lines 12-30; inner layer, bonding layer, outer layer).

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5. Claims 18 – 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Euteneuer (4,952,357). Euteneuer discloses a non-compliant medical balloon (fig 2b), comprising a base having a polymer that extends along a longitudinal axis (fig 1), a first fiber positioned in parallel relation to a longitudinal axis of the balloon (fig 2b), a second fiber wound radially over the base layer along at least a portion of its longitudinal axis (2b), and a film that secures the first fiber to the second fiber so that the first and second fiber are restricted from substantial relative movement during inflation and deflation of the balloon (col 1 lines 65-68), wherein the film comprises a polyimide fiber (col 2 line 68), wherein the second fiber is positioned substantially perpendicular to first fiber (fig 4), wherein the first fiber comprises a plurality of fibers and each are substantially equal in length to the longitudinal length of the base layer (fig 2), wherein the second fiber extends over a longitudinal length of the base (fig 2), wherein the first fiber comprises a plurality of first fibers (fig 4), wherein each of the fibers is substantially equally spaced from each other (fig 4), and wherein the second fiber is substantially equally spaces in each of its radial winds about the base (fig 4), wherein the first fiber and the second fiber are inelastic (col 2 lines 49), wherein the fibers are comprised of a material selected from the group consisting of Kevlar, Vectran, Spectra, Dacron, Dyneema, Terlon (PBT), Zylon (PBO), Polyamide (PIM), or ultra high molecular weight polyethylene and combinations thereof (col 2 lines 66-67), where the film is comprised of a polymer or copolymer, wherein at least one of the base and film are comprised of polyethylene, PET, polycaprolactam, polyester, polyether, polyamide, polyurethane, polyimide, ABS copolymer, polyester/polyether block copolymer, ionomer resin, liquid

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crystal polymer, or rigid rod polymer (col 2 lines 67). Euteneuer discloses the invention further comprising an adhesive (col 2 lines 48-68), wherein the adhesive adheres to the fibers of the first fiber base, wherein the first fiber comprises from about 15 to about 30 fibers disposed adjacent to each other, wherein each of the first fibers has a thickness in the range of about .0005 to about .0001 inch (col 2 lines 54-55), wherein the second fiber is capable of having a wind density in the range of about 50-80 wraps per inch, wherein the second fiber is capable of having a length in the range of about 75-100 inches (col 3 line 34 – 58).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamlin in view of Trotta et al (5,290,306). Hamlin discloses all of applicant's

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invention specifically as claimed with the exception of the fibers having a thickness of about .0005 inch. Trotta et al shows this feature to be old in the medical balloon art (col 4 lines 58). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Trotta et al to modify the balloon of Hamlin by making the fibers about .0005 inches thick for the purpose of making sure it is thin enough so that the balloon may be collapsible down to a smaller diameter.

Response to Arguments

9. Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Campbell et al (5,752,934) disclose a balloon catheter device; Preissman et al (5,728,063) disclose a high torque balloon catheter; Sahatjian et al (5,306,246) disclose a balloon for medical catheter; Bowman et al (4,482,516) disclose a process for producing a high strength porous polytetrafluoroethylene product having a coarse microstructure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melissa A McCorkle
Examiner
Art Unit 3763

MAM
11-8-05



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